**PACKAGE LEAFLET: INFORMATION FOR THE USER**

**HUMULIN® I (Isophane) KwikPen™ 100 IU/ml suspension for injection**
**(insulin, human)**

**Read all of this leaflet carefully before you start using this medicine.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your diabetes specialist nurse, doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your diabetes specialist nurse, doctor or pharmacist.

**In this leaflet**:

1. What Humulin I KwikPen is and what it is used for
2. Before you use Humulin I KwikPen
3. How to use Humulin I KwikPen
4. Possible side effects
5. How to store Humulin I KwikPen
6. Further information


## 1. WHAT HUMULIN I KWIKPEN IS AND WHAT IT IS USED FOR

Humulin I KwikPen is a pre-filled pen containing the active substance human insulin, which is used to treat diabetes. You get diabetes if your pancreas does not make enough insulin to control the level of glucose in your blood (blood sugar). Humulin I is used to control glucose in the long term. Its action is prolonged by the inclusion of protamine sulfate in the suspension.

Your doctor may tell you to use Humulin I KwikPen as well as a fast-acting insulin. Each kind of insulin comes with its own patient information leaflet to tell you about it. Do not change your insulin unless your doctor tells you to. Be very careful if you do change insulin. Each type of insulin has a different colour and symbol on the pack and the pen so that you can easily tell the difference.

## 2. BEFORE YOU USE HUMULIN I KWIKPEN

**Do not use Humulin I KwikPen if you:**
- **think hypoglycaemia (low blood sugar) is starting.** Further in this leaflet it tells you how to deal with mild hypoglycaemia (*see A in Section 4*).
- are allergic (hypersensitive) to human insulin or any of the other ingredients of Humulin I KwikPen (*see Section 6*).

**Take special care with Humulin I KwikPen**
- If your blood sugar levels are well controlled by your current insulin therapy, you may not feel the warning symptoms when your blood sugar is falling too low. Warning signs are listed later in this leaflet. You must think carefully about when to have your meals, how often to exercise and how much to do. You must also keep a close watch on your blood sugar levels by testing your blood glucose often.
- A few people who have had hypoglycaemia (low blood sugar) after switching from animal insulin to human insulin have reported that the early warning symptoms were less obvious or different. If you often have hypoglycaemia or have difficulty recognising the symptoms, please discuss this with your doctor.
- If you answer YES to any of the following questions, tell your diabetes specialist nurse, doctor or pharmacist.

- Have you recently become ill?
- Do you have trouble with your kidneys or liver?
- Are you exercising more than usual?

- The amount of insulin you need may also change if you drink alcohol.
- You should also tell your diabetes specialist nurse, doctor or pharmacist if you are planning to go abroad. The time difference between countries may mean that you have to have your injections and meals at different times to when you are at home.
- Some patients with long-standing type 2 diabetes mellitus and heart disease or previous stroke who were treated with pioglitazone and insulin experienced the development of heart failure. Inform your doctor as soon as possible, if you experience signs of heart failure such as unusual shortness of breath or rapid increase in weight or localised swelling (oedema).

**Using other medicines**
Please tell your doctor or diabetes specialist nurse, if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Your insulin needs may change if you are taking any of the following:
- steroids,
- thyroid hormone replacement therapy,
- oral hypoglycaemics (antidiabetic medication),
- acetylsalicylic acid (aspirin),
- growth hormone,
- octreotide, lanreotide,
- $beta_2$ stimulants (for example ritodrine, salbutamol or terbutaline),
- beta-blockers,
- thiazides or some antidepressants (monoamine oxidase inhibitors),
- danazol,
- some angiotensin converting (ACE) inhibitors (for example captopril, enalapril) or angiotensin II receptor blockers

**Pregnancy and breast-feeding**
Ask your doctor or diabetes specialist nurse for advice before taking any medicine.

The amount of insulin you need usually falls during the first three months of pregnancy and increases for the remaining six months. If you are breast-feeding, you may need to alter your insulin intake or diet.

**Driving and using machines**
Your ability to concentrate and react may be reduced if you have hypoglycaemia (low blood sugar). Please remember this in all situations where you might put yourself and others at risk (e.g. driving a car or operating machinery). You should contact your diabetes specialist nurse or doctor about the advisability of driving if you have:
- frequent episodes of hypoglycaemia
- reduced or absent warning signs of hypoglycaemia.

## 3. HOW TO USE HUMULIN I KWIKPEN

**Always check the pack and the label of the pre-filled pen for the name and type of the insulin when you get it from your pharmacy. Make sure you get the Humulin I KwikPen that your doctor has told you to use.**

Always use Humulin I KwikPen exactly as your doctor has told you. You should check with your doctor if you are not sure.

**Dosage**

- You should normally inject Humulin I as your basal insulin. Your doctor has told you which insulin to use, how much, when and how often to inject. These instructions are only for you. Follow them exactly and visit your diabetes clinic regularly.
- If you change your insulin type (for example from animal to human), you may have to take more or less than before. This might just be for the first injection or it may be a gradual change over several weeks or months.
- Inject Humulin I under the skin. You should not administer it using a different administration route. Under no circumstances should Humulin I be given into a vein.

**Preparing Humulin I KwikPen**
- The KwikPen should be rotated in the palms of the hands 10 times and inverted 10 times immediately before use to resuspend insulin until it appears uniformly cloudy or milky. If not, repeat the above procedure until contents are mixed. Cartridges in the pen contain a small glass bead to assist mixing. **Do not** shake vigorously as this may cause frothing which may interfere with the correct measurement of the dose. The cartridges in the pen should be examined frequently and should not be used if clumps of material are present or if solid white particles stick to the bottom or sides of the cartridge, giving it a frosted appearance. Check each time you inject yourself.

**Getting the KwikPen ready to use (Please see user manual)**
- First wash your hands.
- Read the instructions on how to use your pre-filled insulin pen. Please follow the instructions carefully. Here are some reminders.
  - Use a clean needle. (Needles are not included).
  - Prime your KwikPen before each use. This checks that insulin comes out and clears the air bubbles from your KwikPen. There may still be some small air bubbles left in the KwikPen - these are harmless, but if the air bubble is too big, it may make the dose of your injection less accurate.

**Injecting Humulin I**
- Before you make an injection, clean your skin as you have been instructed. Inject under the skin, as you were taught. **Do not** inject directly into a vein. After your injection, leave the needle in the skin for 5 seconds to make sure you have taken the whole dose. Do not rub the area you have just injected. Make sure you inject at least half an inch (1 cm) from where you last injected and that you 'rotate' the places you inject, as you have been taught.

**After injecting**
- As soon as you have done the injection, unscrew the needle from the KwikPen using the outer needle cap. This will keep the insulin sterile and prevent leaking. It will also stop air going back into the KwikPen and the needle clogging up**. Do not share your needles or your KwikPen.** Replace the cap on the KwikPen.

**Further injections**
- Every time you use a KwikPen you must use a new needle. Before every injection, clear any air bubbles. You can see how much insulin is left by holding the KwikPen with the needle pointing down. The scale on the cartridge shows about how many units you have left.
- Do not mix any other insulin in your disposable pen. Once the KwikPen is empty, do not use it again. Please get rid of it carefully - your diabetes specialist nurse or pharmacist will tell you how to do this.

**If you take more Humulin I than you need**
If you take more Humulin I than you need, your blood sugar may become low. Check your blood sugar *(see A in Section 4*).

**If you forget to use Humulin I KwikPen**

If you take less Humulin I than you need, your blood sugar levels may increase. Check your blood sugar.

**If you stop using Humulin I KwikPen**
If you take less Humulin I than you need, your blood sugar levels may become too high. Do not change your insulin unless your doctor tells you to.

If you have any further questions on the use of this product, ask your diabetes specialist nurse, doctor or pharmacist.

## 4. POSSIBLE SIDE EFFECTS

Like all medicines, Humulin I can cause side effects, although not everybody gets them.

**Human insulin may cause hypoglycaemia (low blood sugar). See more information on hypoglycaemia below in the subsection "Common problems of diabetes".**

**Possible side effects**
**Systemic allergy** is very rare (affects less than 1 person in 10,000). The symptoms are as follows:
- fall in blood pressure
- difficulty in breathing
- fast heart beat
- rash over the whole body
- wheezing
- sweating

If you think you are having this sort of insulin allergy with Humulin I, tell your doctor at once.

**Local allergy** is common (affects less than 1 person in 10). Some people get redness, swelling or itching around the area of the insulin injection. This usually clears up in anything from a few days to a few weeks. If this happens to you, tell your doctor.

**Lipodystrophy** (thickening or pitting of the skin) is uncommon (affects less than 1 person in 100). If you notice your skin thickening or pitting at the injection site, change your injection site and tell your doctor.

Oedema (e.g. swelling in arms, ankles; fluid retention) has been reported, particularly at the start of insulin therapy or during a change in therapy to improve control of your blood glucose.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**Common problems of diabetes**

### A. Hypoglycaemia
Hypoglycaemia (low blood sugar) means there is not enough sugar in the blood. This can be caused if you:
- take too much Humulin I or other insulin;
- miss or delay meals or change your diet;
- exercise or work too hard just before or after a meal;
- have an infection or illness (especially diarrhoea or vomiting);
- have a change in your need for insulin; or
- have trouble with your kidneys or liver which gets worse.

Alcohol and some medicines can affect your blood sugar levels.

The first symptoms of low blood sugar usually come on quickly and include the following:
- tiredness
- nervousness or shakiness
- rapid heartbeat
- feeling sick

- headache
- cold sweat

Until you become confident in recognising your warning symptoms, avoid situations such as driving a car, in which you or others would be put at risk by hypoglycaemia.

**Do not use Humulin I if you think hypoglycaemia (low blood sugar) is starting.**

If your blood sugar is low, eat glucose tablets, sugar or drink a sugary drink. Then eat fruit, biscuits, or a sandwich, as your doctor has advised you and have some rest. This will often get you over mild hypoglycaemia or a minor insulin overdose. If you get worse and your breathing is shallow and your skin gets pale, tell your doctor at once. A glucagon injection can treat quite severe hypoglycaemia. Eat glucose or sugar after the glucagon injection. If you do not respond to glucagon, you will have to go to hospital. Ask your doctor to tell you about glucagon.

**B. Hyperglycaemia and diabetic ketoacidosis**

Hyperglycaemia (too much sugar in the blood) means that your body does not have enough insulin. Hyperglycaemia can be brought about by:
- not taking your Humulin I or other insulin;
- taking less insulin than your doctor tells you to;
- eating a lot more than your diet allows; or
- fever, infection or emotional stress.

Hyperglycaemia can lead to diabetic ketoacidosis. The first symptoms come on slowly over many hours or days. The symptoms include the following:
- feeling sleepy
- flushed face
- thirst
- no appetite
- fruity smell on the breath
- feeling or being sick

Severe symptoms are heavy breathing and a rapid pulse. **Get medical help immediately.**

If hypoglycaemia (low blood sugar) or hyperglycaemia (high blood sugar) are not treated they can be very serious and cause headaches, nausea, vomiting, dehydration, unconsciousness, coma or even death.

***Three simple steps*** *to avoid hypoglycaemia or hyperglycaemia are:*
- Always keep spare syringes and a spare vial of Humulin I.
- Always carry something to show you are diabetic.
- Always carry sugar with you.

**C. Illness**

If you are ill, especially if you feel sick or are sick, the amount of insulin you need may change. **Even when you are not eating normally, you still need insulin.** Test your urine or blood, follow your 'sick rules', and tell your diabetes specialist nurse or doctor.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via **Ireland:** HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, e-mail: medsafety@hpra.ie, **United Kingdom:** Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. HOW TO STORE HUMULIN I KWIKPEN

Keep out of the reach and sight of children.

Before the first use, store your Humulin I KwikPen in a refrigerator (2°C – 8°C). **Do not freeze**. Keep your 'in-use' Humulin I KwikPen at room temperature (below 30°C) for up to 28 days. Do not keep your 'in-use' pen in the fridge. Do not put it near heat or in the sun.

Do not use Humulin I KwikPen after the expiry date which is stated on the label and the carton. The expiry date refers to the last day of that month.

Do not use Humulin I KwikPen, if clumps of material are present or if solid white particles stick to the bottom or sides of the cartridge, giving it a frosted appearance. Check this each time you inject yourself.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. FURTHER INFORMATION

**What Humulin I KwikPen contains**
The **active substance** is human insulin. Human insulin is made in the laboratory by a 'recombinant DNA technology' process. It has the same structure as the natural hormone made by the pancreas. It is therefore different from animal insulins. The human insulin in Humulin I is available in a suspension together with protamine sulfate.

The **other ingredients** are protamine sulfate, metacresol, phenol, glycerol, dibasic sodium phosphate $7H_2O$, zinc oxide and water for injection. Sodium hydroxide or hydrochloric acid may have been used during manufacture to adjust the acidity.

**What Humulin I KwikPen looks like and contents of the pack**
Humulin I (Isophane) KwikPen 100 IU/ml suspension for injection is a white, sterile suspension and contains 100 units of insulin in each millilitre (100 IU/ml).
Each Humulin I KwikPen contains 300 units (3 millilitres).
The Humulin I KwikPen comes in a pack of 5.

The Humulin I in your KwikPen is the same as the Humulin I, which comes in separate Humulin I cartridges. The KwikPen simply has a built in cartridge. When the KwikPen is empty you cannot use it again.

**Marketing Authorisation Holder and Manufacturer**
Humulin I KwikPen is made by: Lilly France S.A.S., Rue du Colonel Lilly, 67640 Fegersheim, France.

The marketing authorisation is held by: Eli Lilly and Company Limited, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL, U.K.

It is distributed in the Republic of Ireland by Eli Lilly and Company (Ireland) Limited, Hyde House, 65 Adelaide Road, Dublin 2, Ireland.

**This medicinal product is authorised in the Member States of the EEA under the following names:**
Huminsulin „Lilly" Basal 100 I.E./ml – KwikPen (Austria)
Humuline-KwikPen NPH (Belgium, Luxembourg, The Netherlands)
Humulin N KwikPen (Estonia, Latvia, Lithuania, Poland, Romania)
Huminsulin Basal (NPH) 100 KwikPen (Germany)
Humulin NPH KwikPen (Denmark, Finland, Iceland, Norway, Slovenia, Sweden)
Humulin (NPH) KwikPen (Greece)
Humulina NPH KwikPen 100 (Spain)

Humulin I KwikPen (Ireland, UK)
Umuline NPH KwikPen (France)

**This leaflet was last approved in March 2015.**

**If you would like a large-print version of this leaflet, please phone 01256 315000 (UK) or 01 661 4377 (Ireland)**